NHG RESEARCH QUALITY MANAGEMENT PROGRAM

QUALITÉ

THE PROGRAM WITH A MISSION TO ENSURE AND ENFORCE THE RESPONSIBLE CONDUCT OF RESEARCH MEETING HIGH ETHICAL STANDARDS

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THE PRINCIPAL INVESTIGATOR'S ROLES & RESPONSIBILITIES (Part 4/5 series)

No.7: Ensure that the Investigational Product is Properly Administered and Stored

No.8: Direct all Relevant Site Operations

CONTINUATION OF PARTICIPATION IN CLINICAL TRIALS AT STEP-DOWN CARE FACILITIES

Step-down care facilities, in particular, cater for patients who require inpatient convalescent and rehabilitative care, those who do not have families or caregivers to look after them at home, or where the caregiver is unable to provide the nursing care required.

THE PRINCIPAL INVESTIGATOR'S ROLES & RESPONSIBILITIES

The Principal Investigator (PI) is responsible for the Investigational Product (IP) accountability at the trial site. This includes ensuring proper usage and storage of the IP. The investigator can familiarise himself or herself with the use of the IP through reading the product information leaflet or the Investigator's Brochure.

No.7: Ensure that the Investigational Product is Properly Administered and Stored

Investigational Product (IP) Management Responsibilities

Responsibilities of IP management include, but are not limited to, maintaining proper records for receiving and dispensing the IP, counselling the study participant on the usage of the IP, ensuring that the IP is stored according to the manufacturer's or protocol's requirements.

The PI may choose to delegate some or all the responsibilities of managing the IP to a pharmacist and/or Clinical Research Coordinator. When doing so, the PI needs to ensure that the duties are appropriately delegated. The PI still retains the responsibility of providing supervision and oversight to the proper management and accountability of the IP.

Documentation and Accountability

It is necessary for the PI to maintain records of the IP's delivery to the trial site, the inventory at the site, the amount used by each subject, the return to the sponsor and the destruction of unused products, if applicable.

These records should include dates, quantities, batch/serial numbers, expiration dates *(if applicable)*, and the unique code numbers assigned to the IP and trial subjects.

The PI ought to also provide adequate documentation in the drug accountability/dispensing log and the subjects' medical records that the subjects were provided the doses specified in the protocol. All IP, whether used or unused, should be reconciled.

Storage, Usage and Administration

The PI is responsible for ensuring proper storage and usage of the IP at the site, as specified by the sponsor or as stated in the Institutional Review Board (IRB) approved protocol. Most IP's are required to be stored within a specific range of temperature.

The PI will have to arrange for or purchase appropriate storage equipment if freezing or refrigeration is required. The IP should be stored in a secured location with access limited to authorised personnel only *(e.g. pharmacist or Clinical Research Coordinator)*.

When dispensing the IP to the subject, the PI or delegated personnel need to explain the correct method of usage and check at appropriate intervals that subjects are following the instructions given.

References:

- *Singapore Guideline for Good Clinical Practice (SG-GCP)*
- *NHG PCR SOP 501-A02 Responsibiities of the Research Team*
- *NHG PCR SOP 501-B06 Investigational Product Accountability*